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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/042,904	01/09/2002	Szu-Min Lin	JOHNA.059C2	7469
27777	7590	07/17/2006	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			TURK, NEIL N	
			ART UNIT	PAPER NUMBER
			1743	

DATE MAILED: 07/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/042,904	Applicant(s) LIN ET AL.	
	Examiner Neil Turk	Art Unit 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on May 15<sup>th</sup>, 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 10-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>5/15/06, 5/10/04</u> | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

This Office Action is in response to Applicant's remarks filed on May 15<sup>th</sup>, 2006.

Claims 10-26 are pending.

#### ***Response to Arguments***

Applicant's arguments, see pages 1-2, filed 5/15/2006, with respect to claims 10-26 in view of Moriarty have been fully considered and are persuasive. The rejection of claims 10-26 in view of Moriarty has been withdrawn.

With regard to applicant's submitted terminal disclaimer, examiner has attached a "Statement Under 37 CFR 3.73(b)" form, which is requested to be filled out for approval of the terminal disclaimer. Representative should mark box 1, and box A with filled in Reel and Frame number, and authorized signature.

#### ***Terminal Disclaimer***

The terminal disclaimer filed on October 17<sup>th</sup>, 2005 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US patent 6,360,595 has been reviewed and is NOT accepted.

The assignee has not established its ownership interest in the application, in order to support the terminal disclaimer. There is no submission in the record establishing the ownership interest by either (a) providing documentary evidence of a chain of title from the original inventor(s) to the assignee, or (b) specifying (by reel and

frame number) where such documentary evidence is recorded in the Office (37 CFR 3.73(b)).

### ***Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "screw" of figure 5 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered. The limitation and claim recitation of claim 19 is otherwise indefinite.

The drawings are objected to because it is unclear how the holder 5 is related to the overall syringe/pipette system shown in figure 6A-C. Figures 3A-D are hard to understand through both the brief description in the specification, and through drawings to which it is hard to see where new elements are appearing through the different embodiments. The specification references the coupling of the membrane barrier to the pipette/syringe with regards to figures 3A-C but these figures are shown in an isolated fashion where it cannot be seen how these embodiments relate to the overall pipette/syringe. Figures 6A-C show the overall system but they fail to show the previous details described which would render figures 3A-D comprehensible.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure

is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Claim Objections***

Claim 11 is objected to because of the following informalities: It would appear that the term "method" recited in the preamble of claim 10 should read as "device" to be cohesive with claim 10. Appropriate correction is required.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 10-26 are rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-47 of U.S. Patent No. 6,360,595 to Lin et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant invention are similar to those of the '595 patent, but for the additional presence of a chemical in the claims of the instant invention. The claims of the '595 patent are broader in all respects to those of the instant invention due to the patent's use of "comprising" language which would allow additional components to be present. Further, in defining the barrel component of the '595 patent, Lin et al. teach in the disclosure that the barrel may comprise a reactant, such as sodium bisulfide. Lin et al. also further defines the device as one being capable of determining the presence of an aldehyde, such as OPA.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear the relationship between the recited "at least one chemical reactive with the analyte" in claim 10 and "wherein the barrel comprises a first reactant and a second reactant". It is unclear if the "first reactant and second reactant" are in addition to the "at least one chemical reactive with the analyte", or are these separate and different elements altogether.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 10, and 12-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wainwright (5,171,537) in view of Moriarty (6,045,757). Wainwright discloses an aspirator-type pipetting instrument with a removable hydrodynamically designed pipette tip, comprising a tubular body section 11(barrel), with an integral tapered nozzle section 12 with a bore 13 communicating with section 11, to which a slidable pipette tip 20 is slidably attached and the end (lines 54-58, col. 2, fig. 1&2, lines 18-31, col. 2).

Wainwright also discloses that the body section contains the usual plunger or piston head (barrier within the barrel), which is attached to an operating rod 14 that projects slidably out of the end of section 11 remote from nozzle section 12 (lines 59-63, col. 2). Wainwright discloses that attached to the outer end of rod 14 is the usual operating head 15, which can be used to manually manipulate the aspirator plunger (barrier) in a known manner (means for adjusting the position of the barrier so as to draw up a fixed volume of liquid). Wainwright further disclose that when the fluid is aspirated into the instrument 10, it passes around fluid element 30 through the bore 22 (nozzle) in tip 20 toward nozzle section 12(aspirator section 11, nozzle section12, and tip 20 attachment constitute two "barrels" in fluid communication by means of a nozzle/valve)(lines 1-16, col. 3, fig. 1&2). Wainwright additionally discloses that mounted in the bore 22 in tip 20 and lodged between axially spaced tabs 26 is a spherically shaped element 30, which is coated or impregnated with a reactive receptor substance, and is mounted for



movement within the reaction chamber (lines 28-33, col. 3; lines 1-3, col. 9).

Wainwright discloses that the spherical substrate is coated or contains any of a number of conventional immobilization chemistries designed to link proteins, nucleic acids, or other specific binding ligands by covalent attachment (lines 18-31, col. 2). Wainwright discloses that when a sample is aspirated into the tip, it passes around the outside of the sphere 30 and is exposed to the chemically treated surface, which thus captures molecules that are to be assayed. Wainwright discloses in example 1 a situation in which the coated element 30 was coated with amino silane (as the group listed in claim 10) and reacted with glutaraldehyde (lines 25-42, col. 4; lines 24-27, col. 10) Wainwright does not disclose that the barrier is vapor or gas permeable but liquid impermeable and does not disclose a coupling device for to adapt the barrier to the testing device.

Moriarty discloses a membrane filter pipette tip such as discussed in Office Action dated 01/11/2006. Moriarty discloses that the pipette 10 is used in conjunction with a pipette tip 34. The tip 34 comprises a hollow tube having an upper/proximal end 38 and a lower/distal end 40. The upper end 38 and lower end 40 are separated by a membrane filter 32 extending across the tube, the membrane being porous to allow unrestricted passage of air, but is hydrophobic so as to discourage the passage of liquid (lines 12-21, col. 4). Moriarty also discloses a coupling device and means for adjusting the barrier so as to measure a fixed volume and for supporting the membrane filter within the pipette tip, as recited in claims 14-17 (line 55-, col. 4 – line 8, col. 5). Moriarty also discloses a porous plastic plug (insert adjustable to position the barrier) mounted within the tube 36 with upper and lower surfaces 48 and 50 and side surface engaging the

inner sidewall 44 of the tube to form a tight friction fit for the plug and to function as means for capturing an edge portion 33 of the membrane filter 32. Moriarty discloses in figure 5 that a different structure for holding the membrane filter 32 within the tube 36 to the coupled pipette tip 34 is an annular shoulder 58' (holder for membrane filter 32 to the tube 36 with the pipette tip 34 coupled). With regard to claims 22&23, the insert could also be said to be "U" or "H"-shaped in cross-section (fig. 3&4). It would have been obvious to modify the Wainwright device to include a gas/vapor permeable, but liquid impermeable barrier and a coupling device to adapt the barrier to the testing device, such as taught by Moriarty in order to provide a filter means to keep unwanted passage of liquid into the pipette and prevent contamination and to have a securely mounted membrane within the pipette tube.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wainwright in view of Moriarty. Wainwright does not specially disclose the pipette tip with coated element 30 containing a first reactant and a second reactant. Wainwright does disclose in examples 1-7 the spherical bead having different reactive coatings, and additionally being washed and recoated during assays to test binding results (col. 4-8). Applicant's specification specifies that the compounds (reactants) X and Y may react both at once or in an alternative one compound (reactant) may react with the aldehyde and, if necessary, the second compound may be reacted afterward (specification page 7, figure 1). It would be obvious to modify the Wainwright device to include a second reactant so as to provide an additional reactive coating to be used in the assay after the initial coating is washed, as a comparative result.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Neil Turk whose telephone number is 571-272-8919. The examiner can normally be reached on Mon-Fri 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NT



**YELENA GAKH  
PRIMARY EXAMINER**